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| 10/577,003 | 12/13/2006 | Surender Kharbanda | GENU:005US/10605111 | 1914 |
| 32425 7590 10/05/2010 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701 | | | EXAMINER GUSSOW, ANNE | |
| | | | ART UNIT 1643 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

aopatent@fulbright.com

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/577,003 | Applicant(s) KHARBANDA ET AL. | |
| | Examiner ANNE M. GUSSOW | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-15 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignments</u> |

DETAILED ACTION

1. Claims 1 and 2 have been amended.

Claim 3 has been cancelled.

Claim 15 has been added.

Claims 10-14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 16, 2009.

2. Claims 1, 2, 4-9, and 15 are under examination.

3. The following office action contains NEW GROUNDS of Rejection.

Rejections Withdrawn

4. The rejection of claims 1, 3, 8, and 9 under 35 U.S.C. 102(e) as being anticipated by Holgersson, et al. is withdrawn in view of applicant's amendment to the claims and the new grounds of rejection below.

5. The rejection of claims 1-9 under 35 U.S.C. 103(a) as being obvious over Holgersson, et al. in view of Capon, et al. and Wreschner, et al. is withdrawn in view of applicant's amendment to the claims and the new grounds of rejection below.

NEW GROUNDS of Rejection

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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9. Claims 1, 2, 4-9, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wreschner (a), et al. (US PG PUB 2005/0019324, priority to March 26, 2002) or Hoogenboom, et al. (WO 2003/089451, priority to April 22, 2002) in view of Capon, et al. (US PAT 5,116,964, issued May 26, 1992, as cited on the PTO-892 mailed January 23, 2009) and Wreschner (b), et al. (WO 96/03502, published February 8, 1996, as cited on the IDS filed October 17, 2007).

The claims recite a MUC 1 chimeric protein comprising a first polypeptide sequence and a second polypeptide sequence, wherein said first polypeptide sequence is a MUC1-EC polypeptide wherein amino-terminal tandem repeat sequences of MUC 1-EC are deleted and said second polypeptide sequence is a human immunoglobulin FC polypeptide or a human albumin polypeptide, wherein said MUC 1-EC polypeptide is selected from the group consisting of SEQ ID NO: 15, SEQ ID NO: 17, SEQ ID NO: 19, and SEQ ID NO: 23, wherein said human immunoglobulin FC polypeptide is a human IgG FC polypeptide, wherein said IgG FC polypeptide is a IgG1 or IgG2 FC polypeptide, further comprising a second MUC 1 chimeric protein comprising a human immunoglobulin FC polypeptide, wherein said MUC1 chimeric protein of claim 4 and said second MUC1 chimeric protein form a dimer by means of disulfide bridge formation between the hinge region of the human immunoglobulin FC polypeptide of said MUC1 chimeric protein of claim 4 and the hinge region of the human immunoglobulin FC polypeptide of said second MUC 1 chimeric protein, wherein said MUC1 chimeric protein dimer comprises two different MUC 1-EC polypeptides, wherein said MUC 1 chimeric protein is a fusion protein. A pharmaceutical composition

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comprising the MUC1 chimeric protein of claim 1 and a pharmaceutically acceptable carrier.

Wreschner, (a) et al. teach MUC1 peptides for the inhibition of cell proliferation including sequences identical to the instant SEQ ID Nos. 19 and 23 (see sequence alignments).

Hoogenboom, et al. teach MUC1 peptides including sequences identical to the instant SEQ ID Nos. 19 and 23 (see sequence alignments) for the production of anti-MUC1 antibodies. Wreschner (a) and Hoogenboom do not teach MUC1 chimeric proteins with a MUC1 sequence and an Fc polypeptide. These deficiencies are made up for in the teachings of Capon, et al. and Wreschner (b).

Capon, et al teach hybrid immunoglobulins comprising a ligand binding domain fused to the Fc region which prolong the in vivo plasma half-life of the ligand binding domain and wherein the fusion proteins are assembled as monomers, hetero- or homodimers or multimers (via disulfide bonds) and the Fc region may comprise the constant regions are selected from IgG1, IgG2, IgG3, IgG4, particularly human IgG1, which resulted in chimeric molecules that were efficiently synthesized and dimerized in the absence of any light chain as well as compositions comprising the ligand binding domain-Fc fusion proteins and a pharmaceutical acceptable carrier (see entire document, particularly cols. 4, 6, 8, 10-14, 29, 31, Fig. 8 and Example 4).

Wreschner, (b) et al teach that MUC1 is abundantly expressed in human breast carcinomas and Wreschner, (b) et al teach several forms of MUC1, including receptor proteins MUC1/X, MUC1/Y and MUC1N as well as the extracellular domains and

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sequences thereof and their administration as soluble MUC1/X, MUC1/Y and MUC1N to inhibit the binding of MUC1 ligands, thereby limiting the growth of the breast cancer cells (see entire document, particularly pp. 1-4, 11-13, 15 and Figs. 3-6).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a MUC1-hlgG-Fc fusion protein comprising an extracellular domain of MUC1/X, MUC1/Y or MUC1/V fused to the Fc region of a human IgG, particularly hlgG1 as well as pharmaceutical compositions comprising the MUC1-hlgG-Fc fusion protein and a pharmaceutically acceptable carrier for therapeutic benefit of in human breast cancer patients.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a MUC1-hlgG-Fc fusion protein comprising an extracellular domain of MUC1/X, MUC1/Y or MUC1/V fused to the Fc region of a human IgG, particularly hlgG1 as well as pharmaceutical compositions comprising the MUC1-hlgG-Fc fusion protein and a pharmaceutically acceptable carrier for therapeutic benefit of in human breast cancer patients in view of Wreschner, (a) et al. or Hoogenboom, et al and Capon et al and Wreschner, (b) et al because Wreschner (a) and Hoogenboom teach MUC1 peptides consisting of the instant SEQ ID Nos. 19 and 23, which would have the amino-terminal tandem repeat sequences of MUC1-ED deleted. Further, Capon et al teach hybrid immunoglobulins comprising a ligand binding domain fused to the Fc region which prolongs the *in vivo* plasma half-life of the ligand binding domain and wherein the fusion proteins are assembled as monomers, hetero- or homodimers or multimers (via disulfide bonds) and the Fc region may comprise the

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constant regions are selected from IgG1, IgG2, IgG3, IgG4, particularly human IgG1, which results in chimeric molecules that are efficiently synthesized and dimerized in the absence of any light chain as well as compositions comprising the ligand binding domain-Fc fusion proteins and a pharmaceutical acceptable carrier and Wreschner (b) et al teach that MUC1 is abundantly expressed in human breast carcinomas and Wreschner (a and b) et al teach several forms of MUC1, including receptor proteins MUC1/X, MUC1/Y and MUC1/V as well as the extracellular domains and sequences thereof and their administration as soluble MUC1/X, MUC1/Y and MUC1/V to inhibit the binding of MUC1 ligands, thereby limiting the growth of the breast cancer cells.

Therefore, one of ordinary skill in the art would have been motivated to produce MUC1 fusion proteins comprising the MUC1/X, MUC1/Y or MUC1/V extracellular domain (i.e., comprising SEQ ID Nos. 19 or 23) fused to a human IgG Fc region, particularly the human IgG1 Fc region, which was shown to be efficiently synthesized and dimerize in the absence of any light chain, in order to prolong the in vivo plasma half-life of the soluble MUC1 extracellular domains for inhibiting the growth of breast cancer cells in human patients. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1,5-6 (Fed. Cir. 1983). Thus, it would have been prima facie obvious to one skilled in the art to have produced a MUC1-hIgG-Fc fusion protein comprising an extracellular domain of MUC1/X, MUC1/Y or MUC1N fused to the Fc

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region of a human IgG, particularly hIgG1 as well as pharmaceutical compositions comprising the MUC1-hIgG-Fc fusion protein and a pharmaceutically acceptable carrier for therapeutic benefit of in human breast cancer patients in view of Wreschner (a), et al or Hoogenboom, et al. and Capon, et al and Wreschner (b), et al.

Further, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, one of ordinary skill in the art would reasonably conclude that the MUC1-hIgG-Fc fusion proteins also possesses the same sequences (i.e. structure) and functional properties as those of the MUC1-hIgG-Fc fusion proteins claimed and, therefore, the MUC1-hIgG-Fc fusion protein comprising the sequences of Wreschner (a), et al. or Hoogenboom, et al. and Capon, et al and Wreschner (b), et al would necessarily have the same functional properties.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is

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(571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow
September 29, 2010

/Anne M. Gussow/
Examiner, Art Unit 1643